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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/033,041      | 12/27/2001  | Manfred Wirth        | 930008-2063         | 8607             |

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EXAMINER

STUCKER, JEFFREY J 7

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/11/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-15 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No.(s) 6
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

## **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

### **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin.

### **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office Action. See 37 CFR

1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Patents are not granted for all new and useful inventions and discoveries. The subject matter of the invention or discovery must come within the boundaries set forth by 35 U.S.C. 101, which permits patents to be granted only for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." The term "process" as defined in 35 U.S.C. 100, means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

The instant "use" claim is not a proper process claim under 35 U.S.C. 101. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v.*

Serial Number: 10/033041  
Art Unit: 1648

4

*Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP § 706.03(a).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. The instant claim is indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is unclear what method/process applicant is intending to encompass. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986). Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the

premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim. See MPEP 2173.05(q).

Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "specified fluorescent particles". The labeled viruses could be considered to be "specified". Does applicant mean "control fluorescent particles"? If such an amendment is made, applicant is required to point out the support for such language.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "and especially about" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is not clear if this is to indicate that the reference particles are preferably the same size as the microbes to be quantitated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 rejected under 35 U.S.C. § 102() as being anticipated by Kruth (Atherosclerosis, 1984).

Claim 10 is directed to a kit comprising a fluorogenic polyene macrolide and optionally, fluorescent particles.

The inclusion of fluorescent reference particles is optional, and, thereby not required. The "kit" limitation does not limit the structure of the components. Kruth teaches a fluorescent macrolide, filipin which can label sterols. Thus, the instant invention is anticipated by Kruth.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-9 and 15 are rejected under 35 U.S.C. § 103(a) as obvious over Pizzato et al. in view of Kruth (Atherosclerosis, 1984).

The instant invention is directed to a method of quantifying viral or bacterial particles by labeling the particles with a fluorogenic polyene macrolide, in particular, filipin, and detecting the fluorescence by confocal microscopy. The method can use fluorescent particles as reference standards.

Pizzato et al. teaches detecting and quantitating MLV and HIV with fluorescent antibodies and confocal microscopy, as disclosed throughout the reference. It further teaches that fluorescent microspheres are used as standards. See page 8600, right hand column, under "Estimation of particle size...." On page 8602, right hand column at the end of the paragraph beginning "Physical counting...", it teaches that the reference particles are similar in size to the labeled viruses. The specific wave length is not



set forth but is a quality of the specific fluorescent label and within the skill of the artisan to determine.

Kruth teaches that filipin is fluorescent and has been used as a label for cholesterol. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute filipin for fluorescently labeled antibodies because filipin is a single specific reagent whereas the antibodies have to be produced for a specific antigen and labeled with a fluorescent dye. The substitution of filipin would bypass this preparation and would label sterol containing entities without have to rely on antibodies against virus specific antigens. One would be motivated to do this in order to simplify the preparation of reagents for the actual quantification of microbes from a sample. Thus, the instant invention is obvious over Pizzato et al. in view of Kruth.

Claims 10-14 are rejected under 35 U.S.C. § 103(a) as obvious over Pizzato et al. in view of Kruth (Atherosclerosis, 1984) further in view of Zuk et al. (U.S. Patent No. 4,281,061).

The claims are drawn to a kit comprising a fluorogenic polyene macrolide and optionally, fluorescent particles.

The relevance of Pizzato et al. and Kruth has been given above. Zuk et al. teach that reagents for an assay can be provided as kits as a matter of convenience and to optimize the sensitivity

of the assay in the range of interest (col 22, line 62 - col 23, line 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the necessary components necessary to perform the method as taught by Pizzato et al. and Kruth into a kit as taught by Zuk et al. for the commercial exploitation of the method. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the necessary reagents to perform the immuno-diagnostic assay in a kit format for the convenience and economy of the user. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for the optimization the assay for use in a clinical diagnostic laboratory.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

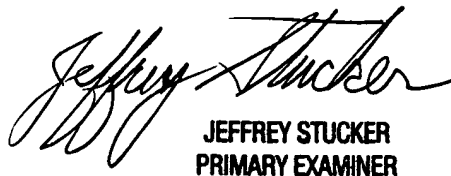
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

Serial Number: 10/033041  
Art Unit: 1648

10

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JEFFREY STUCKER  
PRIMARY EXAMINER